UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

YALE-NEW HAVEN HOSPITAL, INC., et al., Plaintiffs,	:	
-against-	:	No. 3:99CV2546(GLG)
		OPINION
TOMMY G. THOMPSON, Secretary of Health and Human Services,	:	
Defendant.	:	

This action arises from a lingering financial dispute between the Federal government and various hospitals and health care providers over a now-superseded administrative guideline that removed Medicare coverage for investigational medical devices and procedures that had not been approved for marketing by the Food and Drug Administration ("FDA"). Although the guideline was supplanted by regulation over five years ago, numerous reimbursement claims remain outstanding. In this action, Yale-New Haven Hospital ("Yale") and 48 Medicare beneficiaries seek judicial review of a final adverse agency action of the Secretary of Health and Human Services ("Secretary" and "HHS") that denied Medicare coverage for $1.5 million in services involving the surgical implantation of experimental medical devices, provided by Yale to these Medicare beneficiaries. Yale further asks this Court to invalidate the disputed guideline that has prohibited such reimbursement.

Now pending before the Court is the Motion to Dismiss filed by the Secretary of HHS **[Doc. # 17].** HHS asserts that the plaintiffs are collaterally estopped from relitigating the issues presented in this lawsuit because these same issues were litigated by Yale in a prior case, Cedars-Sinai Medical Center v. Shalala, 939 F. Supp. 1457 (C.D. Cal. 1996), aff'd in part and remanded in part, 125 F.3d 765 (9th Cir. 1997), appeal after remand, 177 F.3d 1126 (9th Cir. 1999). Alternatively, HHS argues that the complaint fails to set forth a claim upon which relief may be granted. For the reasons set forth below, the Motion to Dismiss will be DENIED.

BACKGROUND

The Medicare Program

The Medicare program, established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., is a government-sponsored health insurance program that pays for covered medical services provided to eligible aged and disabled individuals. See Cedars-Sinai, 939 F. Supp. at 1460. Medicare "Part A," 42 U.S.C. §§ 1395c-1395i, provides insurance for covered inpatient hospital and related services. Medicare "Part B," 42 U.S.C. §§ 1395j-1395w, is a supplemental program insuring the costs of other items and services, including outpatient hospital and physician services, supplies, and laboratory tests. See Manakee Professional Medical Transfer Service, Inc. v. Shalala, 71 F.3d

574, 577 (6th Cir. 1995). This case concerns the coverage of services under Medicare Part A.

The Medicare program is supervised by the Health Care Financing Administration ("HCFA"), a component administration of HHS, which in turn contracts with private organizations (usually insurance companies), referred to as "fiscal intermediaries," to act as the Secretary's agents in reviewing and paying claims submitted by health care providers under Part A of this program. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100, 424.33; see Cedars-Sinai, 939 F. Supp. at 1460. The intermediaries are required by their contracts to give effect to the laws, regulations, rulings, and general instructions issued by HFCA and found in the manuals and intermediary letters, when determining whether and how much payment is to be made to providers for services furnished to Medicare beneficiaries.

To participate in the Medicare program, hospitals enter into "provider agreements" with the Secretary. 42 U.S.C. § 1395cc. The Medicare program then pays the hospitals directly for covered inpatient and outpatient services provided to Medicare beneficiaries less any deductible or coinsurance payments, which are paid by the beneficiaries.

The Medicare Act does not set forth an all-inclusive list of specific treatments and procedures that will and will not be covered. Instead, the Act provides an overriding standard that excludes from coverage all items and services which are not

"reasonable and necessary for the diagnosis and treatment of illness or injury." The Act provides:

> Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis and treatment of illness or injury. . . .

42 U.S.C. § 1395y(a)(1)(A); see also 42 C.F.R. § 411.15(k)(1); Goodman v. Sullivan, 891 F.2d 449, 450 (2d Cir. 1989). The Act, however, does not define the term "reasonable and necessary" but instead leaves that to the Secretary's determination. 42 U.S.C. § 1395ff(a); State of New York ex rel. Bodnar v. Secretary of HHS, 903 F.3d 122, 125 (2d Cir. 1990) ("Bodnar"). The Secretary has carried out this mandate through the promulgation of formal regulations and through instructional manuals and letters to intermediaries and providers setting forth the Secretary's determination of what services will and will not be covered by Medicare. See Wilkins v. Sullivan, 889 F.2d 135, 139 n.6 (7th Cir. 1989).

As part of this overall scheme, Congress also provided for administrative and judicial review of determinations as to coverage and payment. 42 U.S.C. § 1395ff(b). When a request for payment under Medicare Part A is filed with the fiscal intermediary, the intermediary makes the initial determination as to whether the items and services furnished are covered and the amount of any payment due. See 42 C.F.R. §§ 405.702, 405.704(b),

(c)(1); 421.100(a), (b). If a determination of non-coverage is made because the services furnished were not reasonable and necessary, the intermediary further ascertains whether payment can be made on the ground that neither the beneficiary nor the provider knew, or reasonably could have been expected to know, that payment for the services furnished would not be made. See 42 C.F.R. §§ 405.704(b)(12), (c)(2), 411.402. If the provider is dissatisfied with the initial determination, it may seek reconsideration. 42 C.F.R. §§ 405.710, 405.711. Following reconsideration, a provider may request a hearing before an administrative law judge. 42 C.F.R. §§ 405.720, 405.722. If not satisfied with the ALJ's determination, the provider may seek further review by the Medicare Appeals Council. 42 C.F.R. § 405.724; 20 C.F.R. §§ 404.967 - 404.969. The Appeals Council may also take the case on its own motion. 20 C.F.R. § 404.969. A provider that has exhausted all of these administrative remedies may then seek judicial review of the Secretary's final decision under 42 U.S.C. § 1395ff(b)(incorporating 42 U.S.C. § 405(g) of the Social Security Act). See Weinberger v. Salfi, 422 U.S. 749, 762-64 (1975)(Medicare Act, not 28 U.S.C. § 1331, provides for a district court's review of the Secretary's final determinations); Heckler v. Ringer, 466 U.S. 602, 610-11 (1984)(requiring exhaustion of administrative remedies before judicial review of an adverse decision of the Secretary denying Medicare payments); State of New York v. Lutheran Center for the Aging, Inc., 957 F.

Supp. 393, 396 (E.D.N.Y. 1997); Manakee Professional Medical Transfer Service, 71 F.3d at 577-78.

The Challenged Medicare Manual Provision

The administrative guideline at issue in this case, published in both the Medicare Hospital Manual, § 260.1(B), and the Medicare Intermediary Manual, § 3151.1 (referred to by the parties as the "manual provision"), first appeared in July 1986[1] and reads as follows:

> Devices Not Approved by FDA. – Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary for the diagnosis or treatment of illness or injury . . . Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by the FDA.

(Final Decision of Medicare Appeals Council dated 10/29/00 at 2.) This manual provision was identified as a "New Policy" and given a prospective effective date of July 15, 1986.

Prior to 1986, the Secretary had issued instructions to its intermediaries stating that Medicare pays for a particular medical device or associated service based upon its general acceptance "by the professional medical community as an effective

[1] Prior to 1986, the fiscal intermediaries regularly reimbursed the hospitals for services involving the use of an investigational medical device. See Cedars-Sinai, 939 F. Supp. at 1461. Indeed, after the manual provision was added, the intermediaries did not begin to enforce the instruction until August 1994. (Compl. ¶ 26.)

and proven treatment for the condition for which it is being used" or for the "rarely used, novel, or relatively unknown" treatment or service, based upon authoritative evidence of its safety and effectiveness. (Part A and Part B Intermediary Letters Nos. 77-4 and 77-5.) Thus, a certain amount of discretion was afforded the intermediaries in determining whether reimbursement would be made by Medicare for investigational devices and the services associated with their implantation.

Contrary to these earlier instructions, however, the new 1986 manual provision eliminated the intermediaries' discretion in this regard. In other words, the new provision adopted a "per se" rule that medical devices not approved by the FDA for marketing were not reasonable and necessary.

Under this provision, the devices not covered are defined by reference to the FDA's regulation of medical devices under the Medical Devices Amendments Act of 1976. See 21 U.S.C. §§ 360(k), 360c, 360e, 360j. Under the Medical Devices Amendments Act, before a medical device may be commercially distributed or marketed, notification must be given to the FDA so that the device can be classified according to the degree of regulatory control necessary to insure its safety and effectiveness. See 21 U.S.C. §§ 360(k), 360c(a)(1), (b)(1). Devices are classified as Class I, Class II, or Class III. As for Class I and Class II devices, the FDA requires only notification under 21 U.S.C. § 360(k) prior to marketing. However, Class III devices, those for

which there is insufficient information to determine that the regulatory controls available to the FDA will provide a reasonable assurance of the device's safety and effectiveness, 21 U.S.C. §§ 360c(a)(1)(C), 360e, are treated differently and require "premarket approval" from the FDA before they may be commercially distributed. This typically entails the submission of an application by the manufacturer demonstrating a reasonable assurance that the device is safe and effective. 21 U.S.C. §§ 360c(a)(1)(C), 360e; 21 C.F.R. Pt. 814.

In 1980, the Secretary promulgated regulations providing an exemption to the premarket approval requirement for Class III investigational devices used in clinical trials.[2] Under this investigational device exemption ("IDE"), a Class III device may be lawfully sold to hospitals and physicians for use in clinical trials prior to obtaining premarket approval. 21 U.S.C. § 360j(g); 21 C.F.R. Pt. 812; see Cedars-Sinai, 939 F. Supp. at 1460.

This case involves services furnished by Yale to 48 Medicare beneficiaries in 1994 and 1995[3] for the implantation of Class III

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[2] Clinical trials in each of the hospitals are monitored by an Institutional Review Board ("IRB"), comprised of physicians, researchers and other individuals who are charged under the Secretary's regulations with protecting the welfare of patients receiving investigational drugs, treatment or devices. 21 C.F.R. Pt. 56.

[3] Although there are 48 individual beneficiaries, there were 49 claims for services, since one beneficiary had two separate admissions.

medical devices that had received IDE's but which had not been approved for marketing by the FDA.[4] According to Yale, most of the devices at issue that were involved in clinical trials represented design changes in, or designs similar to, devices already approved by the FDA for general marketing, and all of the devices were expected to provide equivalent or improved functioning as compared to treatment utilizing an alternative procedure or device with FDA pre-marketing approval.[5] (Compl. ¶ 15.)

HCFA and the Secretary have taken the position that the 1986 manual provision prohibits payment for services involving the implantation of IDE devices, even though they have been approved for use in clinical trials and are exempt from general FDA pre-marketing approval requirements for that purpose. (Compl. ¶ 24.) Nevertheless, according to plaintiffs, from 1986 until August 1994, the Secretary and Medicare intermediaries continued to pay

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[4] Specifically, the devices at issue were one or more types of cardioverters-defibrillators-pacemakers and their connecting leads (Ventak PRx 1705, Ventak PRx II 1715, Ventak P2 1625, Endotak C-0072, Endotak C-0074 and Endotak SQ-0048), which had been approved for investigational use by the FDA at the time the devices were implanted but had not been approved for general marketing.

[5] Yale cites as examples the automatic implantable defibrillators used in 1994 to treat potential sudden cardiac death, which were refinements in technology of devices approved by the FDA. These automatic implantable defibrillators had transvenous leads which "dramatically reduced the need for open chest surgery to affix FDA-approved leads directly to the heart." (Compl. ¶ 15.)

for services in which IDE devices were used. (Compl ¶¶ 26, 32.)

Despite the publication of the new policy in the 1986 manual, no regulations implementing this policy were promulgated by the Secretary until 1995. On September 19, 1995, the Secretary published final regulations addressing coverage of IDE devices. Noting that historically,

> HCFA has interpreted the statutory terms "reasonable" and "necessary" to mean that a device must be safe and effective, medically necessary, and not experimental. For most Medicare coverage purposes, the term experimental has been used synonymously with the term investigational. Therefore, a device categorized by the FDA as being investigational served as an indication that it was not "reasonable" and "necessary" within the meaning of the Medicare program. As a general rule, these devices currently are not covered.

60 Fed. Reg. 48418 (Sept. 19, 1995). Acknowledging that "devices that are refinements of existing technologies or replications of existing technologies by other manufacturers . . . could be viewed as ‹reasonable' and ‹necesssary' under Medicare," id., the Secretary characterized such refinements and replications as non-experimental/investigational devices that are eligible for coverage. 42 C.F.R. §§ 405.205, 405.209, 405.211.

Under the new regulations, the FDA assigns devices that have received IDE's to one of two categories: Category A (experimental/investigational) or Category B (non-experimental/investigational) depending on whether initial questions as to the device's safety and effectiveness have been

resolved. 42 C.F.R. §§ 405.201(b); 405.203. The intermediaries may approve coverage for any non-experimental/investigational IDE device in Category B if all other coverage requirements have been met. Id.; 42 C.F.R. § 405.211(b). According to plaintiffs, over 90% of the investigational medical devices sold to the hospitals for use in clinical trials fall within that category. (Compl. ¶ 35.) These regulations, which took effect on November 1, 1995, superseded the manual provision challenged in this case.

Other Litigation

This lawsuit is not the first to challenge the 1986 policy guidelines. In a sealed qui tam action pending in the Western District of Washington, a relator alleged that approximately 130 hospitals knowingly submitted to Medicare false claims for payment of services involving investigational medical devices, in violation of the False Claims Act. See Cedars-Sinai, 125 F.3d at 769.

Additionally, on May 1, 1995, Yale and twenty-four other hospitals challenged these guidelines in an action filed in the Central District of California, the Cedars-Sinai litigation. The medical devices in that case, like the instant action, were Class III medical devices used by the hospitals in clinical trials. Cedars-Sinai, 939 F. Supp. at 1460. The complaint in that action alleged that the 1986 manual provision was unlawful because it was not promulgated in accordance with the ruling-

making requirements of the Administrative Procedures Act, 5 U.S.C. § 553 ("APA"), and the Medicare Act, 42 U.S.C. § 1395hh. The hospitals sought a declaration that the Secretary's policy of not paying for investigational devices and the associated services was without force and effect because of the lack of compliance with required rule-making procedures. Cedars-Sinai, 939 F. Supp. at 1462. The complaint also sought to enjoin the Secretary from enforcing the 1986 manual provision and an order compelling the Secretary to comply with the Medicare Act and APA in promulgating new regulations. Id.

The District Court in Cedars-Sinai held that the 1986 manual provision was a substantive rule subject to the notice-and-comment rule-making provision of the APA, with which the Secretary had not complied. Accordingly, the Court declared the provision invalid ab initio. Id. On appeal, Ninth Circuit remanded the case to the District Court for the limited purpose of determining whether the hospitals' claims filed in 1995, challenging a 1986 policy, were barred by the six-year statute of limitations applicable to actions for judicial review of agency regulations under the APA, 28 U.S.C. § 2401(a). Cedars-Sinai, 125 F.3d at 767, 771. On remand, the District Court held that the statute of limitations defense had not been waived by the Secretary and that the hospitals' claim was therefore time-barred. See Cedars-Sinai, 177 F.3d at 1128. On appeal, the Ninth Circuit affirmed. Id. The Court held that the hospitals'

cause of action challenging procedural irregularities in the promulgation of the manual provision accrued at the time the manual provision was issued, not when the hospitals' claims were denied. Id. at 1129. However, the Court noted that

> [w]ere the Hospitals maintaining a cause of action under the Medicare Act for specific claims allegedly wrongfully denied by the government, they could legitimately contend that they were not injured until the particular denial had occurred. See 42 U.S.C. § 405(g)(requiring plaintiffs to wait until their applications are denied before suing to recover benefits).

Id. Additionally, the Court rejected the hospitals' arguments that the limitations period had been equitably tolled and that the Government should be equitably estopped from raising a limitations defense because of its delayed enforcement efforts. Id. at 1130. Accordingly, the judgment of the District Court dismissing the complaint as time-barred was affirmed.

The Administrative Proceedings Leading to This Appeal

In connection with the qui tam action, the Secretary's Office of the Inspector General issued a subpoena to Yale, seeking information concerning services billed to Medicare involving the use of investigational devices approved by the FDA for use in clinical trials at Yale. Following Yale's response to the subpoena, Yale's Medicare intermediary issued a letter indicating that HCFA required Yale to identify all claims that involved the implantation of cardioverter defibrillator devices

with dates of service on or after March 31, 1994. The intermediary determined that Medicare had overpaid an estimated $1.5 million for 49 billings involving these devices and stated that it would recover this amount by withholding payments from subsequent Medicare revenues otherwise due to the Hospital. Subsequently, individual denial notices were issued.

Yale then requested reconsideration of these denials and, in each case, the intermediary upheld the denials finding that the items and services were not "reasonable and necessary." Yale then pursued its administrative appeal rights, requesting a hearing before an administrative law judge ("ALJ"). In June, 1996, the ALJ concluded that because the District Court in the Cedars-Sinai litigation had declared the manual provision void ab initio, it was of no force and effect. Therefore, after reviewing each case on a patient-by-patient basis, he concluded that each of the devices at issue was generally accepted by the medical community and each was medically reasonable and necessary for the particular beneficiary's condition. Based on these findings, the ALJ determined that the services related to the implantation of the devices were covered by Medicare.

The HCFA Regional Office then filed a protest of the ALJ's decisions with the Appeals Council, requesting review of these decisions. The Appeals Council on its own motion assumed jurisdiction to review the ALJ decision. It then stayed further action in the proceedings awaiting a decision of the Ninth

Circuit in the Cedars-Sinai litigation. On June 28, 1999, following the Ninth Circuit's decision in Cedars-Sinai, the Appeals Council ruled that the manual provision remained valid and reversed the ALJ's decision. Yale submitted its comments to the proposed decision and, on October 29, 1999, the Appeals Council issued its final decision holding that there was no coverage for the services provided by Yale involving these IDE devices which had not been approved for marketing by the FDA. The Appeals Council further held that there was no evidence in the record that any of the 48 beneficiaries knew or had reason to know that the services would not be covered by Medicare and, therefore, they would not be personally liable. (Final Decision at 5.) However, it found that Yale was on constructive notice of the Medicare provision at issue since 1986, and, therefore, was liable for the costs of these services. Id. at 6. The Appeals Council noted hypothetically that even if the Ninth Circuit had affirmed the District Court's decision in Cedars-Sinai, it would have remanded this case to the ALJ for further consideration because the record contained insufficient evidence that the devices in question, at the time they were implanted, had been proven safe and effective or that they were generally accepted in the medical community as safe and effective for the condition for which they were used. Id. at 4 n.3.

This decision constituted the final decision of the Secretary. Yale, individually and on behalf of the 48 Medicare

beneficiaries, then filed this action seeking judicial review of this final decision.[6] Yale's amended complaint sets forth four counts as to why the decision of the Secretary should be reversed. Counts One and Two allege that the decision of the Secretary is invalid because it is based on the 1986 manual provision which was invalid for failure to comply with the notice and comment rulemaking provision of the APA and was contrary to the Medicare statute, 42 U.S.C. § 1395hh. Count Three challenges the Secretary's decision as arbitrary and capricious because it is based on substantively invalid manual provision and because it ignores uncontradicted evidence in the record that the services furnished were reasonable and necessary for the treatment of the patients involved. Count Four is directed at the Secretary's finding that Yale knew or reasonably could have been expected to know of the noncoverage for these medical devices. Yale asserts that this finding is invalid because the manual provision is procedurally and substantively invalid, and it ignores Yale's belief that the devices were reasonable and necessary for the treatment of elderly sick patients, and further ignores the consistent history of payment by the Medicare program for these

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[6] Yale's initial complaint sounded in five counts. In partial response to the motion to dismiss, Yale filed an amended complaint **[Doc. # 21]**, which tracks the original complaint almost verbatim. Count Five, however, has been dropped, and Counts Three and Four were expanded somewhat. Defendant's reply brief addressed the counts as amended. Therefore, the Court will rule on the motion to dismiss as it relates to the amended complaint.

devices and the fact that use of the devices was an acceptable standard of practice in the local medical community. The Secretary has moved to dismiss all four of these counts.

DISCUSSION

I. Whether the Rulemaking Violations Asserted in Counts One and Two of the Complaint Are Barred by Collateral Estoppel

The primary ground for dismissal raised by the Secretary is that Yale is collaterally estopped from challenging the validity of the manual provision, based upon HHS's failure to comply with the rulemaking provision of the APA, 5 U.S.C. § 553, and the Medicare Act, 42 U.S.C. § 1395hh.[7] The Secretary maintains that Yale has already litigated this issue and lost in the Cedars-Sinai litigation and, thus, is precluded from relitigating this issue in the instant case. Yale, on the other hand, maintains that collateral estoppel does not preclude this timely statutory appeal of a final adverse decision of the Secretary. Further, it asserts that the Ninth Circuit's ruling that the Cedars-Sinai litigation was time-barred under 28 U.S.C. § 2401 does not bar

[7] The Medicare Act, 42 U.S.C. § 1395hh(a)(1), directs the Secretary to prescribe such regulations as may be necessary to carry out the administration of the Medicare program. In October 1986, a new subsection (b) was added to the statute, which directs the Secretary, with certain exceptions, to provide notice and an opportunity for public comment before issuing regulations under subsection (a)(1) of the statute. In 1987, § 1395hh was further amended to provide that no rule, requirement or restatement of policy establishing or changing a substantive legal standard governing the scope of benefits under Medicare shall take effect unless it is promulgated by the Secretary as a regulation under subsection (a)(1). 42 U.S.C. § 1395hh(a)(2).

its challenge to the validity of the manual provision, which was ruled void ab initio by the District Court and which decision was never overruled on the merits.

Collateral estoppel, or issue preclusion, bars a party from relitigating in a second proceeding an issue of fact or law that was litigated and actually decided in a prior proceeding, if that party had a full and fair opportunity to litigate the issue in the prior proceeding and if the decision on the issue was necessary to support a valid and final judgment on the merits. See Metromedia Co. v. Fugazy, 983 F.2d 350, 365 (2d Cir. 1992), cert. denied, 508 U.S. 952 (1993); Gelb v. Royal Globe Insurance Co., 798 F.2d 38, 44 (2d Cir. 1986), cert. denied, 480 U.S. 948 (1987); Zdanok v. Glidden Co., Durkee Famous Foods Division, 327 F.2d 944, 955 (2d Cir.), cert. denied, 377 U.S. 934 (1964); see generally Parklane Hosiery Co. v. Shore, 439 U.S. 322, 326 n. 5 (1979); Restatement (Second) of Judgments § 27 (1982). In Transaero, Inc. v. La Fuerza Aerea Boliviana, 162 F.3d 724, 731 (2d Cir. 1998), cert. denied, 526 U.S. 1146 (1999), the Second Circuit listed the four essential elements that must be present before the doctrine of collateral estoppel will be applied to bar a party from raising a specific factual or legal issue in a second action: (1) the issues in both proceedings are identical; (2) the issue in the prior proceeding was actually litigated and actually decided; (3) there was a full and fair opportunity to litigate ths issue in the prior proceeding; and

(4) the issue previously litigated was necessary to support a valid and final judgment on the merits. See also In re. PCH Associates, 949 F.2d 585, 593 (2d Cir. 1991). The party seeking the benefit of collateral estoppel bears the burden of establishing the identity of the issues and that the same issue was actually and necessarily determined in a prior litigation. Connors v. Tanoma Mining Co., 953 F.2d 682, 684 (D.C. Cir. 1992); Ottley v. Sheepshead Nursing Home, 784 F.2d 62, 65 (2d Cir. 1986); see also 18 Moore's Federal Practice 3d § 132.03[3][a] (3d ed. 2000).

In this case, Count One of the complaint alleges that the decision of the Secretary should be reversed because it is based on a manual provision that is invalid because of the Secretary's failure to comply with the notice-and-comment rulemaking provision of the APA. (Compl. ¶ 56.) Count Two challenges the Secretary's decision because it is based on a manual provision that is contrary to the Medicare statute, 42 U.S.C. § 1395hh. (Compl. ¶ 58.) Neither count raises the issue upon which judgment was entered in the Cedars-Sinai litigation. The Ninth Circuit held that the six-year statutory time-bar of 28 U.S.C. § 2401 prevented Yale and the other hospitals from pursuing their claims against the government. The Court expressly noted, however, that if the hospitals were asserting a cause of action under the Medicare Act for specific claims that were wrongfully denied, as in the instant case, their claims would not accrue

until the denial had occurred and, therefore, they would not be barred by § 2401. Cedars-Sinai, 177 F.3d at 1129.

More important to the collateral estoppel issue, however, is the fact that although the Cedars-Sinai litigation clearly involved the same issues as raised in Counts One and Two, the Ninth Circuit never reached the substantive merits of the validity of the 1986 manual provision. The substantive issues presented by this litigation were not essential to, nor even a part of, the judgment in the Cedars-Sinai case. The judgment was based solely on the statute of limitations issue, not on whether the Secretary's promulgation of the manual provision violated the rulemaking requirements of the APA. "In order to operate as an estoppel . . . the determination of the issue must have been essential to the judgment." Tucker v. Arthur Andersen & Co., 646 F.2d 721, 728 (2d Cir. 1981). If an issue is not necessary to a prior judgment, relitigation of that issue is not barred in a subsequent proceeding. See Brown v. Felsen, 442 U.S. 127, 139 n.10 (1979); In re. PCH Associates, 949 F.2d at 593; Jim Beam Brands Co. v. Beamish & Crawford Ltd., 937 F.2d 729, 734 (2d Cir. 1991), cert. denied, 502 U.S. 1094 (1992); see also 18 Moore's Federal Practice 3d §§ 132.03[3][a] & [4]][a] (3d ed. 2000)(stating that issue preclusion operates to preclude relitigation of only those issues necessary to support the judgment entered in the first action. Relitigation is not foreclosed if the decision of the issue was not necessary to the

judgment reached in the prior litigation.)

Moreover, although a judgment adverse to Yale was entered in the Cedars-Sinai litigation following the second appeal, 177 F.3d at 1130, neither of the substantive issues raised by Counts One and Two in this litigation was decided adversely to Yale by the Ninth Circuit. In fact, the District Court decided the issues raised in Count One favorably to Yale, holding that the manual provision was void ab initio because of the Secretary's failure to comply with the rulemaking provision of the APA. That decision was never reversed on the merits by the Ninth Circuit.[8]

> Relitigation of an issue is not precluded if the party against whom issue preclusion is sought could not, as a matter of law, have obtained review of the judgment in the original action . . . . For example, a winning party may not appeal issues determined adversely to it by the trial court and, as a consequence, is not barred from relitigating those issues.

18 Moore's Federal Practice 3d § 132.03[4][k] (3d ed. 2000). Obviously, Yale would not have appealed the District Court's favorable ruling concerning the validity of the manual provision. That issue was not reviewed by the Ninth Circuit, and Yale is not barred from challenging the validity of the manual provision in the instant case.

Collateral estoppel bars relitigation of a particular issue

[8] Although the District Court decided the issue raised by Count Two, the validity of the manual provision under § 1395hh, adversely to Yale, see Cedars-Sinai, 939 F. Supp. at 1463, that issue was never reviewed on appeal.

that has been "both actually litigated and actually decided." In re. PCH Associates, 949 F.2d at 593; see also United States v. Hussein, 178 F.3d 125, 129 (2d Cir. 1999); In re. Drexel Burnham Lambert Group, Inc., 148 B.R. 993, 998 (S.D.N.Y. 1992). It does not bar relitigation of an issue that was decided favorably to the party against whom collateral estoppel is asserted but reversed on other grounds inapplicable to the present litigation, and where the merits of the issue were never addressed by the appellate court.

Accordingly, we hold that the doctrine of collateral estoppel or issue preclusion does not prevent the plaintiffs in this appeal of an adverse agency decision from litigating the issues raised in Counts One and Two of their complaint.

II. Whether the Contention in Count Three That the Secretary Was Legally Obligated to Make Individual Determinations of Medical Necessity Is Foreclosed by Second Circuit Precedent

In Count Three, plaintiffs maintain that the decision of the Secretary was arbitrary and capricious because it "ignores uncontradicted evidence in the record that the services furnished were reasonable and necessary for the treatment of the patients involved." (Compl. ¶ 59.) The Secretary asks this Court to dismiss this Count on the ground that it overlooks that portion of the Appeals Council's decision that the evidence was insufficient to establish that the devices were safe and effective or generally accepted by the medical community at the

time of their implantation. Appeals Council Decision at 4 n.3. Further, the Secretary urges this Court to dismiss Count Three because it presupposes that the Secretary has a legal duty to make a case-by-case inquiry as to whether the medical services provided to each patient were reasonable and necessary, a theory that they claim was rejected in Goodman v. Sullivan, 891 F.2d 449 (2d Cir. 1989).

In Goodman, the Second Circuit affirmed the District Court's dismissal of a Medicare beneficiary's challenge to a regulation under Medicare Part B, which prohibited payment for experimental, investigational or unproven treatment or diagnostic methods not generally accepted in the medical profession. The plaintiff had argued that this regulation was invalid because the Medicare Act requires coverage for all medically necessary services and, therefore, the Secretary should not be able to deny coverage for experimental procedures that a physician has determined to be medically necessary. The Court held that, although the Medicare Act barred payment for services "not reasonable and necessary," that did not affirmatively mandate coverage for all reasonable and necessary services. Id. at 450.

Based on Goodman, the Secretary argues that, even assuming the services provided to the 48 Medicare beneficiaries in this case were reasonable and necessary, the Secretary had no duty to determine reasonable necessity on a case-by-case basis and, therefore, his decision cannot be arbitrary and capricious. We

do not agree with the Secretary's interpretation of Goodman as prohibiting a challenge to a final decision on the grounds that the procedures were medically necessary.

The third count challenges the very substance of the Secretary's final decision denying Medicare coverage for the 49 claims. The Secretary asks this Court to dismiss this claim as a matter of law without any review of the administrative record or a consideration of the merits of the appeal. In essence, what the Secretary is asking would deny Yale the judicial review to which it is entitled under the Medicare Act. If this Court were to uphold the validity of the manual provision and hold that the manual provision removes all discretion from the intermediaries concerning payment for investigational devices that have not received premarket approval from the FDA, then the Secretary would be correct that the medical necessity of the procedures at issue is legally irrelevant to the issue of coverage under Medicare. However, the Court has not yet ruled on the validity of the manual provision and, if it is declared invalid, then the issue of whether there is substantial evidence[9] to support the

[9] The standard of substantial evidence requires "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401 (1971)(quoting Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938); see also Bodnar, 903 F.2d at 126; Hurley v. Bowen, 857 F.2d 907, 912 (2d Cir. 1988). In determining whether the decision is supported by substantial evidence, the reviewing court reviews the record as a whole. "This means that in assessing whether the evidence supporting the Secretary's position is substantial, we will not

Secretary's determination that the procedures were not medically necessary would become relevant. See St. Mary's Hospital of Troy v. Blue Cross & Blue Shield Ass'n, 788 F.2d 888, 890 (2d Cir. 1986).

Accordingly, we decline to dismiss the third count at this time.

III. Whether the Secretary's Waiver-of-Liability Determination is Based on Factual Allegations That Have No Legal Bearing on That Issue

Count Four of the complaint takes issue with Secretary's determination that Yale either knew or should have reasonably been expected to know that services related to investigational or experimental medical devices would not be covered. The Secretary maintains that Count Four fails to set forth a viable claim for relief because none of the allegations on which it is based is legally relevant to a waiver of financial liability under 42 U.S.C. § 1395pp. See 42 C.F.R. § 411.406(e)(1).

Section 1395pp(a) provides in relevant part that where a determination is made that services furnished to an individual by a provider are not reasonable and necessary within the meaning of 42 U.S.C. § 1395y(a)(1), payment shall nevertheless be made if

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look at that evidence in isolation but rather will view it in light of other evidence that detracts from it." Bodnar, 903 F.2d at 126. As the Court in Bodnar makes clear, the Secretary's discretion in determining Medicare reimbursements is not boundless. The Secretary's decision still must be supported by substantial evidence. Klementowski v. Secretary of Health & Human Services, 801 F. Supp. 1022, 1027 (W.D.N.Y. 1992).

neither the individual nor the provider knew, or could reasonably have been expected to know, that Medicare would not provide reimbursement for the items or services in question. The criteria for making this determination are set forth in the regulations at 42 C.F.R. § 411.406. Under this section, a provider is deemed to have actual or constructive knowledge of an exclusion from coverage if any one of four sets of conditions are met, including the circulation of an exclusionary policy in HCFA notices, manual issuances, bulletins, or other written guidelines or directives. 42 C.F.R. § 411.406(e)(1). The Secretary found that the manual provision had been made available to Yale in 1986 and, on that basis concluded that Yale reasonably should have known that the services associated with these devices would not be covered by Medicare. The Secretary asserts that the grounds advanced by Yale for reversing that decision, e.g., that the devices were reasonable and necessary, the history of payment for these devices, the conclusion of the peer review organization that the services were reasonable and necessary, are legally irrelevant to this determination. Yale, on the other hand, maintains that the regulations themselves include information from intermediaries and peer review organizations as relevant to the determination of whether the provider knew or reasonably could have been expected to know of the noncoverage. Yale claims that the intermediaries and peer review organizations communicated to it that payment would be made, and in fact

payment was made, for investigational devices approved for clinical trials. Moreover, Yale states that even the manual does not state that investigational devices used in clinical trials would not be covered.

At this juncture we are reviewing Yale's fourth count on a motion to dismiss filed pursuant to Rule 12(b)(6), Fed. R. Civ. P. Such a motion tests only the sufficiency of the complaint and should not be granted unless it appears beyond doubt that the plaintiff can prove no set of facts in support of its claim that would entitle it to relief. Conley v. Gibson, 355 U.S. 41, 45-46 (1957). The issue is not whether the plaintiff will prevail but whether it is entitled to offer evidence in support of her claim. Villager Pond, Inc. v. Town of Darien, 56 F.3d 375, 378 (2d Cir. 1995), cert. denied, 519 U.S. 808 (1996). In ruling on a motion to dismiss, we accept as true all allegations of the complaint and draw all reasonable inferences in favor of the plaintiff. Still v. DeBuono, 101 F.3d 888, 891 (2d Cir. 1996).

Yale has alleged that, at a minimum, it received conflicting information as to whether these investigational devices would receive Medicare coverage. The fact that the intermediaries continued to pay for these services for a period of eight years after the manual provision was disseminated could reasonably be interpreted by Yale that payment would continue to be made. At a

minimum, based on the allegations of the complaint, Yale has created an issue of fact for trial. Accordingly, we deny defendant's motion to dismiss the fourth count.

Conclusion

For the foregoing reasons, defendant's motion to dismiss **[Doc. # 17]** is DENIED. SO ORDERED.

Date: August 31, 2001.
Waterbury, Connecticut.

_____/s/_____
GERARD L. GOETTEL,
United States District Judge